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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,424	10/09/2001	Sudhirdas K. Prayaga	15966-585CIP2 (Cura-85CIP	8925

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/973,424	PRAYAGA ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-48 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESTRICTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 27-28, 33, 36, 39, and 47, drawn to isolated polypeptides and the therapeutic use of said polypeptides in vivo, classified in classes 530 and 514, subclasses 300 or 350, and 2 respectively.

II. Claims 5-13, 29-30, 34, 37, and 39, drawn to isolated nucleic acids, vectors encoding nucleic acids, and the therapeutic use of said nucleic acids in vivo, classified in classes 536, 435, and 514, subclasses 23.1, 320.1, and 44 respectively.

III. Claims 15-17, 31-32, 35, 38-39, and 48, drawn to antibodies and the therapeutic use of said antibodies in vivo, classified in classes 530 and 424, subclasses 187.1 and 130.1 respectively.

IV. Claims 14, 25, and 26, drawn to cells transfected with a nucleic acid encoding a polypeptide and in vitro test methods using said cells, classified in classes 435, subclasses 325 and 7.21.

V. Claims 18 and 42, drawn to the detection of a polypeptide in vitro, classified in class 435, subclass 7.1.

VI. Claims 19-22 and 43-46, drawn to the detection of a nucleic acid in vitro, classified in class 435, subclass 6.

VII. Claim 23-24, drawn to a method of identifying an agent that binds to a polypeptide, classified in class 435, subclass 7.1.

VIII. Claims 40-41, drawn to methods of screening compounds using test animals which recombinantly express a polypeptide, classified in class 800,

subclass 3.

The inventions are distinct, each from the other because of the following reasons.

1) Inventions I-IV are patentably distinct in that polypeptides, nucleic acids, antibodies, and cells expressing a protein are substantially different in structural, physical, and biological properties, are made using different reagents and methods, and can be used for substantially different purposes. In particular, note that the polypeptide can be made synthetically and does require the nucleic acid, and that the antibody can be naturally occurring and does not require the polypeptide for its manufacture. Further, while cells transfected with a vector do utilize the nucleic acid, the transfected cells are structurally and functionally different from isolated nucleic acids and vectors. Further, the nucleic acids and vectors can be used for purposes other than making transfected cells, such as their use in in vitro hybridization assays. In regards to in vivo administration, it is further noted that nucleic acids, polypeptides, and antibodies have completely different modes of operation in vivo based on the different biological properties of the compounds.

2) Inventions I-IV are patentably distinct from inventions V-VIII in that the nucleic acids, polypeptides, and antibodies can be used for substantially different purposes than the in vitro testing or diagnostic methods of inventions V-VII, such as their use for therapy in vivo. Further, the methods of screening of invention VIII do not require the use of the antibodies or polypeptides of inventions I or III. In regards to the nucleic acids and cells of invention II and IV, the nucleic acids and cells can be used for substantially different purposes than in the screening methods using a test animal of invention VIII, such as their use in in vitro detection methods, or in vivo therapeutic methods.

3) Inventions V-VIII are patentably distinct in that the diagnostic and screening methods of the different inventions utilize substantially different reagents which operate under substantially different chemical conditions.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classification, and different search requirements, restriction for examination purposes as indicated is proper.

Applicant is further required under 35 U.S.C. 121 to elect a single nucleic acid or amino acid sequence from amino acid sequences SEQ ID NOS: 2, 5, 7, 66, and 68 and nucleotide sequences SEQ ID NOS: 1, 4, 6, 65, and 67 for prosecution on the merits. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a).

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. Likewise, amino acid sequences corresponding to different polypeptides are also structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141.

Should applicant traverse on the ground that the species of nucleotides or amino acids are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Monday-Friday from 10:30-7:00. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242. Please note that Official papers can no longer be received by the examiner's direct Rightfax number.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER